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PTO/SB/21 (02-04)

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<b>TRANSMITTAL FORM</b> <i>(to be used for all correspondence after initial filing)</i>		Application Number	09/751,271
		Filing Date	December 28, 2000
		First Named Inventor	Alferness et al.
		Art Unit	3743
		Examiner Name	K. Odlund
Total Number of Pages in This Submission	7	Attorney Docket Number	29912-701.201

ENCLOSURES (Check all that apply)		
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SIGNATURE OF APPLICANT, ATTORNEY OR AGENT	
Firm or Individual name	James R. Shay, Reg. No. 32,062, WILSON SONSINI GOODRICH & ROSATI
Signature	
Date	January 24, 2005

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**REPLY BRIEF**

Atty. Docket No. 29912-701.201

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re application of )  
)  
Alferness et al. )  
)  
Appln. No.: 09/751,271 )  
)  
Confirmation No.: 8995 )  
)  
Filed: December 28, 2000 )  
)  
"Mitral Valve Constricting )  
Device, System and Method" )

Group Art Unit: 3743

Examiner: K. Odlund

**APPELLANTS' REPLY BRIEF PURSUANT TO 37 C.F.R. § 1.193**

**MAIL STOP APPEAL BRIEF - PATENTS**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

Appellants submit the following reply brief in accordance with the provisions of 37 C.F.R. § 1.193 in response to the Examiner's Answer mailed December 3, 2004. This brief is being filed in triplicate. Please charge any required fee to Deposit Account No. 23-2415.

**RESPONSES TO ARGUMENTS RAISED IN EXAMINER'S ANSWER**

This Reply Brief responds to arguments raised by the Examiner in the Examiner's Answer.

Group I: Claim 25

Claim 25 stands rejected under 35 U.S.C. § 102(e) as anticipated by Houser. A rejection for anticipation under § 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference with sufficient precision and detail to establish that the subject matter existed in the prior art. The reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it. In her analysis of claim 25, however, the Examiner repeatedly fails to give weight to each and every limitation of the claim. In addition, the Examiner repeatedly picks and chooses among features of alternative embodiments described in Houser to come up with hybrid subject matter that did not exist in the prior art.

For example, the Examiner argues that Houser clip 498a shown in Figure 42B is "generally C-shaped" and can be delivered via the coronary sinus. "[Clips 498] will have to be C-shaped for proper clamping, as shown in figures such as 31B." (Examiner's Answer at p. 4) However, claim 25 requires the clip to have an effective radius less than a dilated mitral valve annulus. Clip 498a of Figures 42B-D does not meet this radius limitation. In fact, Houser's specification does not address the relative radii of clip and mitral valve annulus with respect to any embodiment delivered via the coronary sinus. The Examiner's argument improperly fails to address this claim limitation.

The Examiner also argues that "the embodiment of figures 27A and 27B are [sic] not unlike appellants[']". She quotes Houser ¶ 128 by indicating that the clip of Figures 27A and 27B "may be delivered and placed over or around the valve by a variety of different methods." The Examiner concludes that "it is within a reasonably broad interpretation that any of the clips disclosed such as that shown in figures 27A and 27B can be delivered via the coronary vasculature as discussed in sections [0134]-[0140]." (Examiner's Answer at pp. 3-4)

The Examiner, however, is looking at one Houser embodiment for the device and another for the delivery method. In fact, as shown in Houser Figure 28, the deployed clip 406 of Figures 27A and 27B lies outside of the coronary sinus 398. Houser never says that clip 406 can or should be delivered to that location via the coronary sinus or that it would partially encircle the mitral valve while it was in the coronary sinus if it were delivered by that route. Rather, Houser's discussion of a completely different embodiment mentions the coronary sinus delivery of clips that can be placed across the top of the mitral valve outside of the coronary sinus, such as shown in Figures 42, without partially encircling the mitral valve and without having an effective radius less than a dilated mitral valve annulus, as required by claim 25.<sup>1</sup> Houser does not anticipate claim 25.

Group II: Claims 26 and 28

Claims 26 and 28 stand rejected under 35 U.S.C. § 102(e) as anticipated by Houser. Claim 26 limits claim 25 by stating that the advancing step includes releasably coupling the constriction device to an elongated flexible introducer and moving the constriction device into the coronary sinus with the introducer. The Examiner points to a dictionary definition of "couple" as being "to link together; connect," then proceeds to ignore this definition by concluding that the "releasably coupling" limitation of claim 26 is met by *contact* between Houser's plunger 448 and the clip, as shown in Houser Figure 37. While Appellants do not necessarily agree that the American Heritage dictionary sets forth the meaning of "couple" within the context of this patent application, mere contact between the Houser plunger and the Houser clip is not a releasable coupling under the dictionary definition or as used in this patent application. The Examiner has therefore failed to show how Houser anticipates claim 26 under § 102(e).

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<sup>1</sup>In fact, although claim 25 stands rejected under § 102(e), the Examiner's analysis resembles an obviousness argument under § 103. Even if the Examiner's rejection of Houser was an obviousness argument based on § 103, however, the argument would fail because of her impermissible use of hindsight to combine features of embodiments without any suggestion in the prior art that such a combination would be possible or desirable.

Claim 28 limits claim 26 by adding a step of placing a cylindrical sheath within the coronary sinus. In her argument with respect to the rejection of this claim under § 102(e) the Examiner argues that “sheaths are extraordinarily well known in the art and introducers are commonly within sheaths. This feature is so well known in the catheter art that it would be obvious to one with ordinary skill in the art to include a sheath as a guide for the introducer for the purpose of more controlled delivery.” (Examiner’s Answer at p. 6) An obviousness argument, however, has no place in a rejection under § 102. The Examiner has not shown how Houser anticipates claim 28 under § 102(e).

Group III: Claims 27 and 29

Claim 27 stands rejected under 35 U.S.C. § 102(e) as anticipated by Houser. Claim 27 depends from claim 26 and recites the step of releasing the introducer from the constriction device when the constriction device at least partially encircles the mitral valve. Once again the Examiner cites a dictionary definition of “couple” as being “to link together; connect,” and once again the Examiner equates “contact” with “couple”:

In a reasonably broad interpretation, the introducer assembly of Houser most certainly has a connection with the clip in order for it to be deployed. A plunger/introducer assembly as discussed by Houser can be considered a releasable coupling, for when the plunger forced the clip out of the housing they are released from contact. When they reside in the introducer at some point they are contacting each other in a connecting manner.

(Examiner’s Answer at pp. 6-7) As stated above, while Appellants do not necessarily agree that the American Heritage dictionary sets forth the meaning of “couple” within the context of this patent application, mere contact between the Houser plunger and the Houser clip is not a releasable coupling under the dictionary definition or as used in this patent application.

Furthermore, the Examiner has completely ignored the limitation of claim 27 that the release occurs when the constriction device at least partially encircles the mitral valve. Houser does not disclose or address this limitation. The Examiner has therefore failed to show how Houser anticipates claim 27 under § 102(e).

APPELLANTS' REPLY BRIEF UNDER 37 C.F.R. §1.193  
U.S. Appln. No. 09/751,271  
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Claim 29 stands rejected under 35 U.S.C. § 103(a) as being obvious in view of Houser. Like claim 27, claim 29 recites the step of releasing the introducer from the constriction device when the constriction device at least partially encircles the mitral valve. As discussed above, Houser does not disclose this method step. Furthermore, the Examiner has not otherwise met her burden of showing how the prior art in general discloses or suggests this limitation. The invention of claim 29 therefore would not have been obvious in view of Houser under § 103(a).

APPELLANTS' REPLY BRIEF UNDER 37 C.F.R. §1.193  
U.S. Appln. No. 09/751,271  
Docket No. 29912-701.201

**CONCLUSION**

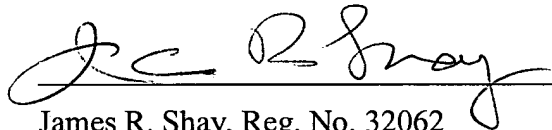
For the reasons stated above and in Appellant's Appeal Brief, claims 25-30 are patentable over the prior art of record, and the rejections those claims under 35 U.S.C. § 102(e) and § 103(a) are improper and should be withdrawn. Appellants respectfully ask the Board to overturn the Examiner's rejection with instructions to allow the claims.

The USPTO is directed and authorized to charge all required fees to Deposit Account No. 23-2415.

Respectfully submitted,

Date: \_\_\_\_\_

1/24/05



James R. Shay, Reg. No. 32062